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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,777	12/03/2003	Manoj Monga	A-2826-AL	7087
7590	10/19/2005		EXAMINER	
Kenneth K. Vu 22872 Avenida Empresa Rancho Santa Margarita, CA 92688			CRAIG, PAULA L	
			ART UNIT	PAPER NUMBER
			3761	

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/727,777	MONGA, MANOJ	
	Examiner	Art Unit	
	Paula L. Craig	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 8/31/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-14, 17, 18, 20-27 and 31-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-14, 17, 18, 20-27 and 31-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8/31/2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>8/31/2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Objections to Drawings and Claims

1. The objection to the drawings under 37 CFR 1.83(a) for Claim 18, for not showing every feature of the invention specified in the claims, is maintained as per reasons of record.
2. Applicant's amendments to the drawings and specification filed August 31, 2005, are sufficient to overcome the remaining objections in the prior action mailed June 9, 2005.
3. Claim 1 and new Claims 36 and 38 are objected to because of the following informalities: Claim 1 is lacking a period at the end of the claim. Claims 36 and 38 include the limitation "may be coupled to the tubular member by a tether". It is not clear to the Examiner whether the tether is being claimed or not. Appropriate correction is required.

Response to Amendment and Arguments

4. Applicant's amendment and arguments filed August 31, 2005, with respect to the claim rejections of Claims 6-7, 22, 24, 27, and 32 under 35 U.S.C. 112, second paragraph; of Claims 1-3, 5, 6, 8-14, 18, 23, 25-27, and 33 under 35 U.S.C. 102(b) over U.S. Patent No. 3,606,889 to Arblaster; of Claims 1-3, 7, 25, and 26 over U.S. Patent No. 5,906,575 to Conway et al.; Claims 15, 16, 28, and 29 under 35 U.S.C. 103(a) over Arblaster in view of U.S. Patent No. 6,793,651 to Bennett et al.; of Claim 4 under 35

U.S.C. 103(a) over Arblaster in view of Miller; of Claim 17 under 35 U.S.C. 103(a) over Arblaster in view of U.S. Patent No. 4,705,510 to Rosenberg; of Claims 19, 20, 30, and 31 under 35 U.S.C. 103(a) over Arblaster in view of Conway; of Claim 21 under 35 U.S.C. 103(a) over Arblaster in view of Conway and Rosenberg; and Claims 22 and 32 under 35 U.S.C. 103(a) over Arblaster in view of Conway and U.S. Patent Publication No. 2003/0060807 to Tanghoj et al.; have been fully considered and are persuasive. The rejections of these claims on these bases have been withdrawn. However, upon further consideration, a new ground of rejection is made for Claims 1-6, 8-14, 17-18, 20-27, and 31-39; see below.

Claim Rejections - 35 USC § 103

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claims 1-3, 5-6, 8-14, 18, 20, 22-23, 25-27, and 31-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arblaster in view of U.S. Patent No. 5,556,385 to Andersen.
7. For Claim 1, Arblaster shows a drainage catheter having a tubular member and a drainage lumen, as stated in the prior office action mailed June 9, 2005. The tubular member has a proximal end and a distal end; the drainage lumen extends from the proximal end to the distal end of the tubular member (Fig. 3). A retention member is formed around the tubular member, which is adapted to move between a low-profile state facilitating insertion of the drainage catheter and a high-profile state facilitating

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retention of the drainage catheter in a body cavity (Figs. 1 and 3). Arblaster shows a connector hub at the proximal end; the connector hub includes a port (Fig. 1). The tubular member and retention member of Arblaster are capable of operating to seal and tamponade an access tract in the body cavity, as stated in the prior office action.

Arblaster shows a rubber plug for the inflation lumen (Fig. 1).

8. For independent Claim 25, Arblaster teaches a drainage catheter having a tubular member, with the tubular member having an access lumen extending longitudinally; a drainage portion having a drainage port; a retention member formed around the tubular member and adapted to move between a low-profile state facilitating insertion of the drainage catheter and a high-profile state facilitating retention of the drainage catheter in a body cavity; a connector hub at a proximal end of the tubular member including a port and a lumen plug; and the tubular member and the retention member operating to seal and tamponade an access tract in the body cavity, as stated in the previous office action.

9. For independent Claims 1 and 25, Arblaster does not expressly show an access lumen plug. Andersen teaches a percutaneous catheter which may be used for removal of fluid from a patient's body (col. 1, lines 10-14). The catheter has an access lumen plug which is integral with the connector hub (plug 36, Figs. 1 and 2, col. 5, lines 31-39). The plug closes the lumen and helps to avoid confusion between different lumens (col. 5, lines 31-38). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the catheter of Arblaster to include an access

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lumen plug integral with the connector hub, to close the lumen and help to avoid confusion between different lumens, as taught by Andersen.

10. Arblaster teaches the limitations of Claims 2, 3, 5, 6, 8-14, 18, 23, 26-27, and 33, as stated in the prior office action.

11. For Claim 24, Arblaster teaches the body cavity in which the retention member facilitates retention of the drainage catheter being the body cavity of an animal. See Arblaster, col. 1, lines 30-43).

12. For Claims 20 and 31, Arblaster teaches the access lumen providing easy draining of the body cavity (Fig. 3). Arblaster does not expressly show the access lumen plug. Andersen shows an access lumen plug as stated above in paragraph 7. The access lumen plug taught by Andersen is capable of providing easy draining of the body cavity (Figs. 1 and 4 and col. 1, lines 10-14). It would have been obvious to modify the catheter of Arblaster to include an access lumen plug providing easy draining of the body cavity.

13. For Claims 22, 32, and 36-39, Arblaster does not expressly show an access lumen plug. For Claims 22 and 32, Anderson teaches an access lumen plug that operates like a snap-on plug (Figs. 1 and 2, col. 3, lines 30-37, and col. 5, lines 33-39). For Claims 36 and 38, the plug of Andersen may be coupled to the tubular member by a tether (flexible band 38, Figs. 1 and 2 and col. 5, lines 33-35). For Claims 37 and 39, the access lumen plug includes a protruding portion that may be pushed into the proximal end of the access lumen to seal the access lumen (Figs. 1 and 2). For Claims 22, 32, and 36-39, it would have been obvious to modify the catheter of Arblaster to

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include an access lumen plug that operates like a snap-on plug with a tether and a protruding portion that may be pushed into the lumen, as taught by Andersen, to close the lumen and help to avoid confusion between different lumens; see paragraph 9 above.

14. For Claims 34 and 35, neither Arblaster nor Andersen expressly show the tubular member having a length between about 8 cm to about 12 cm or about 4 cm to about 8 cm. The length of the tubular member is a result effective variable, since it affects the fit of the catheter to the individual patient. The discovery of an optimum value of a result effective variable is ordinarily within the ordinary skill in the art. See *In re Boesch and Slaney*, 205 USPQ 215 (CCPA 1980).

15. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arblaster in view of Andersen, as stated above, and further in view of Miller. Arblaster and Andersen do not show the tubular member and the retention member in the low-profile state having a diameter of about 8 Fr – 10 Fr. Miller discloses catheters having French sizes of 8.5 and 10, and states that the French size may be adjusted according to the needs of the patient (col. 4, lines 11-22). It would have been obvious to modify the catheters of Arblaster and Anderson to a size of 8 Fr – 10 Fr as taught by Miller to suit a particular body cavity or a particular patient.

16. Claims 17 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arblaster in view of Andersen, as stated above, and further in view of Rosenberg.

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17. Arblaster and Andersen do not show the tubular member or the access lumen plug being made of a soft, silicone material including a radiopaque material. Rosenberg shows a nephrostomy catheter constructed from an elastic material such as silicone, with radiopaque material included to enhance visualization and assist in correct placement of the catheter under radiologic vision, as stated in the prior office action. It would have been obvious to modify the catheter of Arblaster to include manufacture of the tubular member or the access lumen plug from a soft silicone material with radiopaque material, in order to enhance visualization of the catheter as taught by Rosenberg.

Conclusion

18. The newly cited prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,092,850 to Buma shows a catheter having a snap-on plug which is integral with a connector hub.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

20. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paula L. Craig whose telephone number is (571)272-5964. The examiner can normally be reached on 8:30AM-5:00PM M-F.

22. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on (571)272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

23. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paula L Craig
Examiner
Art Unit 3761

PLC

TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER
